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NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/729,935	NINOMIYA ET AL.	
	Examiner	Art Unit	
	Jyoti Chawla	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II (claims 5-16) in the reply filed on July 2, 2007 is acknowledged. The traversal is on the ground(s) that the seasoning of group I is made by the process of Group II. This is not found persuasive because Inventions of Group II and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product claimed (Group I, claims 1-4) can be made with another and materially different process, i.e., a process wherein "preparing a solid koji" is not required or wherein the addition of "lactic acid bacterium" is not required.

Because these inventions are independent or distinct for the reasons as indicated above and the previous office action, the requirement for restriction is still deemed proper. Claims 5-16 are pending and 1-4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected product. This Election is made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the instant case claim 5 step (ii) recites "hydrolyzing the protein by adding a solution to the resulting solid koji at an amount approximating to a salt concentration not inhibiting

the hydrolysis of the protein to form unrefined soy and then fermenting the unrefined soy," which does not enable one of skill in the art to be able to follow the method and make or use the invention as recited.

A number of factors must be considered in assessing the enablement of an invention, including the following: the breadth of the claims, the amount of experimentation necessary, the guidance provided in the specification, working examples provided, predictability, and the state of the art. See *In re Wands*, 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Circ. 1988). The claim as recited, requires a salt concentration in the solution that would be non-inhibiting to the hydrolysis of the proteins in solid koji, however, different fungal and bacterial strains and their enzymes have different salt tolerances and the determination of the amount of salt that would not inhibit the hydrolysis of proteins in a solution for a particular combination of koji fungus and lactic acid bacteria would require an undue amount of experimentation on the part of one of skill in the art.

Furthermore, other factors, such as temperature, pH of the fermentation solution, concentration of solutes (other than salt) in the fermentation solution, time allotted for hydrolysis, fermentation atmosphere and conditions etc., that determine whether a certain salt level can inhibit the protein hydrolysis in addition to the specificity of strain of fungus or bacteria in the koji and fermentation solution. Thus the claim as recited would require undue experimentation on the part of one of skill in the art.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Since the microorganism(s) Lactobacillus lactis FERM BP 08552 is/are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism(s)

is/are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit(s) of the microorganism(s). The specification does not disclose a repeatable process to obtain the microorganism(s) and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. If the depository is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 5-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5, step (ii) recites "hydrolyzing the protein by adding a solution to the resulting solid koji at an amount approximating to a salt concentration not inhibiting the hydrolysis of the protein to form unrefined soy and then fermenting the unrefined soy". It is not clear from the claim as recited, as to what is encompassed in the term "at an amount approximating to a salt concentration not inhibiting the hydrolysis of the protein to form unrefined soy and then fermenting the unrefined soy solution is added to the solid koji" as recited. It is unclear as to what "unrefined soy" is and how is the unrefined soy, different from "resulting solid koji". It is also unclear as to what kind of solution is added to the solid koji, i.e., is it a salt solution or a sugar solution or solution with one or more microorganisms.

Further the phrase "at an amount approximating to a salt concentration" is unclear as to what is being added to an amount approximating to a salt concentration. Also it is also not clear as to what is the amount approximating the salt concentration is . It is further unclear as to what kind of salt is being recited in the claim, i.e., is the salt common salt (sodium chloride) or a calcium salt or potassium salt or some other salt. Thus the claim as recited fails to convey the nature of added solution, the concentration of the substance being added and the amount of the solution that is being added to the solid koji in step (ii).

It is unclear as recited in claim 5, if the alcohol and acetic acid concentrations are requirements of the process or the characteristics of the final product made or have been added to the end product in some other way.

Claim 6 is indefinite as recited, as it is unclear whether the percentage of salt is measured in the unrefined soy during the hydrolysis of protein step or before the

fermentation step or after the fermentation step. Claim 6, as recited is unclear as fermentation would result in sugar utilization thus the percentage of other ingredients in the resulting solution after fermentation, including salt, would change as compared the percentage before fermentation.

The term "raw material" in claims 5, 7 and 8 is a relative term, which renders the claim indefinite. The term "raw material" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Regarding claims 5, 7 and 8, it is unclear as to what is encompassed by the term "raw material" as the defatted soybean is modified and swelled as recited in claim 8, i.e., the soybean has been processed and modified and may not be considered as raw material by one of skill in the art.

Claim 9 is indefinite for the recitation of "wherein (ii) is carried out at 5-40^0 C for 40-144 hours" as it is unclear as to whether the time and the temperature recited covers the hydrolysis of proteins or it covers the fermenting of the unrefined soy or both. Clarification and or correction is required.

Claim 10 is indefinite for the recitation of "wherein the unrefined soy in step (ii) is at pH 4-10", as it is unclear at what part of the step (ii) is the pH of the unrefined soy in the recited range. It is also unclear as to whether the soy is considered unrefined soy before hydrolysis, during or after hydrolysis, or during or after fermentation, or during the entire process.

Claims 11 and 12 are indefinite for the recitation of "wherein nitrogen of a volume 2- to 10-fold (5 to 8 fold) the volume of the headspace of the fermentation tank is purged to the headspace above the unrefined soy and then the tank is sealed in (ii)." As it is unclear, as recited, whether there is one tank or there are two tanks (one fermentation tank and another in which unrefined soy is kept). Also, the headspace in the tank or tanks as recited would be determined by the size of the tank and the batch-size of unrefined soy in the tank. Furthermore, it is unclear whether the fermentation tank is closed with nitrogen atmosphere maintained inside the tank by a closed pipe system or if the fermentation tank is closed after purging with nitrogen once only or any other form

of modified atmosphere is maintained in the fermentation tank. Thus the claim as recited in unclear for the purposes of prior art comparison.
Claims 5, 13 and 14 are indefinite for the recitation of "microorganisms with protein hydrolysis potency". The metes and bounds of the term "protein hydrolysis potency" as recited are unclear. The enzymes such as hydrolases, proteases, peptidases etc., have protein hydrolysis potency. As recited, it is unclear as to whether the microorganisms added to koji have protein hydrolysis potency (i.e., proteases etc.,) or external enzymes having the protein hydrolysis potency have been added to the koji in addition to the microorganisms.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Determining the scope and contents of the prior art.
Ascertaining the differences between the prior art and the claims at issue.
Resolving the level of ordinary skill in the pertinent art.
Considering objective evidence present in the application indicating obviousness or nonobviousness.

(A) Claims 5-7, 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baensch et al (US 5965178) in view of Takebe et al (US6303161 B1)

Baensch et al hereinafter Baensch, teaches a seasoning composition and method of making the seasoning fermentation of plant based protein material (Column 2, lines 55-

62) as instantly claimed. The reference teaches of a process of producing the seasoning comprising:
(i) preparing koji is fermented in the solid state (i.e., solid koji) by inoculating koji mold on vegetable protein source to make koji (Column 2, lines 50-67). Koji mold taught by the reference includes Aspergillus, such as Aspergillus oryzae, and Aspergillus sojae (Column 2, lines 50-67), which are the same filamentous fungi as recited by the applicant in claims 13 and 14. Since the reference teaches of the same microorganism (fungi) as recited by the applicant therefore the reference also teaches of a microorganism having the protein hydrolysis potency to hydrolyze the vegetable proteins present in the raw materials (vegetable protein material) as instantly claimed.

Regarding step (ii) Baensch teaches of hydrolysis of the fermented solid protein koji in the presence of water with or without the addition of salt (Column 3, lines 1-3), thus the reference teaches of fermenting the koji obtained from the first fermentation of step(i.e., step (i) as recited) and hydrolyzing the protein in a solution with or without salt in a solution that does not inhibit the hydrolysis of the protein to form unrefined soy and then fermenting the unrefined soy.
Regarding the addition of lactic acid bacteria twice to the fermentation mixture once during the fermentation step to make solid koji and secondly during or just before the hydrolysis step, Baensch teaches of the addition of lactic acid bacteria to either in the koji step or during the hydrolysis step (Abstract). The reference further teaches that
1. when the inoculation with a culture of lactic acid bacterium is carried out in the fermented koji stage, the inoculation may take place

- before,
- at the beginning,
- anytime during the fermentation process (Column 2, lines 60-67).

2. when the inoculation is carried out at the hydrolysis stage, the inoculation may take place

- before,
- at the beginning,
- anytime during the hydrolysis process (Column 3, lines 10-14).

Thus Baensch teaches that the lactic acid bacteria can be added either during step (i) or during step(ii) in such a way that the hydrolysis of the proteins can take place in the presence of lactic acid bacteria. The reference does not teach the addition of lactic acid bacteria in both the steps.

Takebe teaches of making soy based fermented health product (by soy sauce fermentation process), where the reference teaches of the addition of lactic acid bacterium as intestine regulating bacterial culture to the vegetable protein soybeans. Lactic acid bacteria are added at the same time as the inoculation of the koji and the period of growth of lactic acid bacteria extends from the period of inoculation of the koji mold to the completion of hydrolysis. Lactic acid bacteria have a good compatibility with the koji mold. The bacteria also propagate well without interfering with the growth of koji mold. Furthermore, addition of lactic acid bacteria at the same time as the addition of the koji mold (i.e., instantly claimed step (i)), enhances the production efficiency of the koji (Column 6, lines 10-51). Takebe further teaches that the lactic acid bacterial population is sustained to the completion of the hydrolysis (i.e., instantly claimed step (ii)) (Column 6, lines 20-51). Thus the reference teaches that the lactic acid bacteria are inoculated along with the koji mold and cultivated during the entire process as is instantly claimed.

Based on the above discussion, the two references teach the following:

- Methods of making fermented seasoning/spice/ hydrolyzed protein/healthful products from vegetable protein source (soy) by the addition of lactic acid bacteria and koji fungus (Aspergillus oryzae, Aspergillus sojae) were known in the art at the time of the invention as taught by Baensch and Takebe.
- Process of making a fermented vegetable protein based seasoning where lactic acid bacteria can either be added to the vegetable protein at the time of koji preparation (i.e. step (i)) or at the time of hydrolysis of the fermented koji (i.e. step (ii)) was also known at the time of the invention (Baensch).

- An effective population of lactic acid bacteria in the fermentation mixture at the time of koji preparation and also at the time of protein hydrolysis provides the benefit of higher degree of release of amino acids in the final product than produced by conventional soy sauce processes when the hydrolysis takes place in the presence of lactic acid bacteria (Baensch, Column 2, lines 30-35, Column 3, lines 60-62).
- Addition of lactic acid bacteria at the time of the inoculation of koji fungus during the time of koji preparation process (i.e., step (i)) was known to increase the efficiency of production because the lactic acid bacteria are compatible with the koji fungus and do not interfere in the growth of the fungus (Takebe).
- Hydrolysis of vegetable proteins takes place faster in the presence of an effective amount of lactic acid bacteria.
- Effective amount of bacteria in the fermentation mixture depends upon various factors, such as, pH (salt concentration), temperature, nutrients, the availability , viability or initial concentration of inoculum and the time period allotted for the bacterial and fungal cultures to grow and ferment the substrates.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Baensch such that lactic acid bacteria be added at either the koji preparation stage (Baensch or Takebe) or during the protein hydrolysis stage (Baensch) or both steps during the process of making a fermented vegetable protein based seasoning. One would have been motivated to do so in order to have an effective population of lactic acid bacteria in the fermentation mixture at the time of koji preparation and also at the time of protein hydrolysis to make a product with higher degree of release of amino acids in the final product than produced by conventional soy sauce processes when the hydrolysis takes place in the presence of lactic acid bacteria (Baensch, Column 2, lines 30-35, Column 3, lines 60-62). One would have been further motivated to add the lactic acid bacteria to the fermentation mixture in a single step or in two or more steps, depending upon various factors of the fermentation media, such as, the pH (salt concentration), temperature, nutrients etc. One would have also been

motivated to add the lactic acid bacteria more than once during the process based on the availability of inoculum, initial concentration or viability of the inoculum. Further the time period required by the bacterial and fungal cultures to ferment the substrates and hydrolyze the proteins would also influence the decision to add the lactic acid bacterial culture once or more times during the process of making a fermented vegetable protein based seasoning/ spice/ healthful product.

Regarding the amount of bacteria added the Baensch reference teaches that the amount of lactic acid bacteria added either at the time of the koji preparation or during the time of hydrolysis in the amount of 10^3 to 10^7 CFU per gram. The concentration of the added bacterial inoculum is less than the recited bacterial concentration of 10^8 to 10^{11} cells per gram. Takebe teaches of addition of an inoculum of 10^3 CFU per gram , which is smaller than the one recited in the claim, however the reference teaches that the bacterial population grows to 1.7 X 10^7 CFU per gram during the preparation of koji and increases to between 2.2 X10^9 to 3.4 X10^9, which falls within the recited range of the applicant. Thus bacterial population in the recited range of the applicant was known at the time of the invention. It would have been well within the purview of one of ordinary skill in the art to either add more bacteria to the culture medium and maintain their population or to add a rapidly multiplying bacterial strain and provide conditions for rapid increase in the population of bacteria in the vegetable protein culture medium. Therefore, to alter the bacterial strain, inoculum concentration or the culture medium to grow and sustain the bacterial population in the vegetable protein based culture medium as taught by Takebe, would not have involved undue experimentation on the part of one of ordinary skill in the art at the time of the invention. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the amount of lactic acid bacteria either during the preparation of koji step or during the hydrolysis step or both, in order to have an effective amount of the bacterial population along with an effective population of koji fungus in the fermentation mixture to make good koji containing intestine regulating lactic acid bacterial culture. One would have been motivated to modify the amount of bacteria added to the koji or hydrolysis solution

as taught by Baensch, based on the nature of lactic acid bacteria (i.e., the strain of lactic acid bacteria chosen), the concentration of solutes especially salt in the fermenting mixture (Column 3, lines 1-10). One would have been also motivated to add the higher concentration of lactic acid producing bacterial culture in order to make the soy based fermented seasoning product as taught by Baensch, in a shorter period of time. One would have been further motivated to modify the amount of lactic acid bacteria based on the pH, of the culture medium and the viability of the bacterial sample.

Baensch teaches of using soybeans as the source of the vegetable proteins (Column 2, lines 57). Baensch also teaches that the soybean is cooked (Column 2, lines 59-60). The reference does not specify the amino acid percent after hydrolysis as instantly claimed. It was known at the time of the invention that cooking of soy beans increases the digestibility of protein by the enzymes from 65-90%, as taught by Wiley's encyclopedia of food Science and technology, (Page 2178), which falls in the applicant's recited range. Baensch teaches of cooking the soybeans as discussed above and cooking the beans or soybean meal increases the protein digestibility to 65-90% or in other words cooking as taught by Baensch, increases the hydrolysis of proteins to form constituent amino acids in the ratio of 65-90%, which falls in the instantly claimed range. Regarding the concentration of isobutyl alcohol, n-butyl alcohol; isoamyl alcohol; and acetic acid, the reference teaches of making a vegetable protein based seasoning/spice/health product by the addition of Aspergillus and lactic acid bacteria (as instantly claimed) by a two-step fermentation process as recited, in the time, temperature and pH in the recited range of the applicant. Since the reference teaches of similar process as instantly claimed, one would expect that the product as produced by the method as taught by Baensch would have similar characteristics to the product as instantly claimed (i.e., a similar concentration of isobutyl alcohol, n-butyl alcohol; isoamyl alcohol; and acetic acid to the instantly claimed product).

NOTE: Regarding the above limitation to claim 5, applicant is further referred to the rejection under 35USC 112 above.

Regarding claim 6, Baensch teaches that the vegetable protein based fermented seasoning can be made with or without salt to the soy during or before hydrolysis (i.e., step (ii))(Abstract, Column 2, lines 8-10, Column 3, lines 1-5). Thus the reference teaches of salt concentration in the unrefined soy as instantly claimed.

Regarding claim 7, Baensch teaches that the raw material containing vegetable protein is soybean (Column 2, lines 57). The reference also teaches that defatted soy was used to make seasonings like soy sauce at the time of the invention (Column 1, lines 16-17). Thus the reference teaches that defatted soybean can be used to make the seasoning as instantly claimed.

Regarding claim 9, Baensch teaches that the hydrolysis step is carried out after the addition of water (i.e., step (ii) as recited) is carried out preferably at 30-45^0 C or 2-20^0 C for a period of 12 hours to 25 days which includes the instantly claimed range of time (Column 3, lines 17-28, also see Column 2, lines 15-22). Thus the reference teaches of hydrolysis time and temperature in the range recited by the applicant.

Regarding claim 10, Baensch teaches, wherein the unrefined soy in (ii) is at pH 4.5 to 10 (Column 2, lines 28-30) as instantly claimed.

Regarding claim 13 and 14, Baensch teaches of filamentous fungi that belong to the genus Aspergillus and specifically from the group consisting of Aspergillus oryzae and Aspergillus sojae (Column 2, lines 53-54), as instantly claimed.

Regarding claim 15, Baensch teaches that the lactic acid bacterium can be a lactic acid bacterium (Column 2, lines 18-20). The reference further teaches that non-limiting examples of lactic acid bacteria which may be used include Lactobacillus sake (L. sake), L. crispatus, L. gasseri, L. johnsonii, L. reuteri, L. rhamnosus, L. curvatus, L.

plantarum, L. helveticus, L. paracasei, L. fermentum, L. alimentarius, L. brevis, L. delbrueckii, L. farciminis, L. acidophilus and other Lactobacillus species, Leuconostoc mesenteroides, Pediococcus pentosaceus, Pediococcus acidilactici, Streptococcus thermophilus, Enterococcus faecalis, Enterococcus faecium and Tetragenococcus halophilus, etc. These organisms may also be used as mixtures of different strains, which may comprise different (two or more) species(Column 2, lines 38-50). Thus the reference teaches of lactic acid bacteria of genus Lactobacillus. Regarding the Lactobacillus lactis, Takebe teaches of addition of lactobacillus lactis and koji fungus to ferment a soy-based product (Column 10, line 61), as is instantly claimed. Thus addition of Lactobacillus as lactic acid bacteria to koji in order to make a soy based fermented seasoning was known in the art (Baensch, Column 2, lines 38-50). Addition of Lactobacillus lactis bacteria along with koji fungus to make koji was also known in the art at the time of the invention. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Baensch and add Lactobacillus lactis as the lactic acid bacteria to ferment koji and hydrolyze proteins. One would have been motivated to add lactobacillus lactis in order to have an easily available and affordable bacterium that has an intestine regulating function as taught by Takebe.

Regarding claim 16, Baensch in view of Takebe teaches that the lactic acid bacterium is Lactococcus lactis (Takebe, Column 10, line 61), however the references do not teach the specific subspecies or strain of the bacterium as recited by the applicant (L. lactis FERM BP-08552). Regarding the reference not disclosing the specific Lactobacillus lactis FERM BP-08552 as is instantly claimed, it is noted that although the bacterial strain as taught by the references Baensch and Takebe is not the same as is recited, however the bacteria taught by Baensch and Takebe are also lactic acid producing bacteria as instantly claimed in claims 5, 15 and 16. The lactic acid bacteria taught by Baensch and Takebe have the following characteristics in common with the claimed enzymatically effective agent as recited:

- Takebe teaches the same genus and species of bacteria (Lactobacillus lactis) as instantly claimed,

- Baensch and Takebe teach addition of the lactobacillus (lactic acid bacteria) in addition to Aspergillus fungus to the soy based substrate to produce koji and soy hydrolysate as is instantly claimed.
- The applicant has not claimed a specific enzyme or enzymatically effective agent or any unexpected result that can be obtained specifically from addition of subspecies L. lactis FERM BP-08552 which can not be obtained from other lactic acid producing bacteria including other lactobacilli as taught by Baensch or L.lactis species as taught by Takebe.

Therefore, the L. lactis FERM BP-08552, as recited by the applicant would appear to be the same taught by Baensch in view of Takebe. Furthermore, even if the enzymatically effective agent is not exactly the same as the one obtained from other lactic acid bacteria including other L. lactis, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute one art recognized functional equivalent (i.e. L. lactis as taught by Takebe) for another (L. lactis FERM BP-08552 as instantly claimed) in hydrolyzing the soybean koji by the method as taught by Baensch, depending on which strain of L.lactis or lactic acid bacterium was more easily available and affordable at the time the invention was made, absent any clear and convincing evidence and arguments to the contrary.

(B) Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baensch in view of Takebe , as applied to claims 1-7 and 9-16 above, and further in view of Arnaud et al (US 3917851).

Baensch in view of Takebe, has been applied to claims 5-7, 9-16, as discussed above. Regarding claim 8, Baensch teaches of cooking the soybeans and used in solid particulate form (Column 2, lines 59-62). Takebe also teaches of modifying and swelling soybean. The references do teach of the particulate form, however, Baensch does not specifically state extrusion cooking as the method of cooking soy. However extrusion cooking of defatted soy was known in the art at the time of the invention as taught by Arnaud et al, hereinafter Arnaud. Arnaud teaches of extrusion cooking of defatted soy for making a fermented soy based product (column 2, lines 15-18 and 25-33). Therefore

it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Baensch and cook the soybean by extrusion cooking method in order to make the protein and carbohydrates of the bean readily available for microbial action. One would have been motivated to use extrusion cooking as the method of cooking the soybean as extrusion cooking is fast and it shortens the processing time for preparation of soybean before inoculation with koji fungus and lactic acid bacteria as instantly claimed.

Regarding the nitrogen solution index (NSI) for the soybean of 8 to 20, it was known in the art at the time of the invention that NSI of cooked soy product typically a flour, with an NSI of about 20 to 60. Since the Baensch reference teaches of a cooked soybean particulate, it would be obvious to one of ordinary skill in the art at the time of the invention that the soy material taught by Baensch would have the NSI characteristics in the range as instantly claimed by the applicant absent any clear and convincing evidence and arguments to the contrary.

(C) Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baensch in view of Takebe , as applied to claims 1-7 and 9-16 above, and further in view of Izumi (US 4008333).

Baensch in view of Takebe, has been applied to claims 5-7, 9-16, as discussed above. Regarding claims 11 and 12, Baensch teaches of method of making a fermented soy based seasoning composition, which utilizes koji fungus and lactic acid bacteria to ferment the soy based substrate. The reference teaches of hydrolysis of proteins where the fermentation may be done either in a single step or in two steps (step (ii) as instantly claimed). The reference does not specifically teach that the hydrolysis takes place anaerobically or without the presence of oxygen. The reference also does not teach of an inert gas replacing the headspace in the fermentation tank. However methods of making fermented soy based seasoning, where the hydrolysis (i.e., step (ii) as recited) takes place in a modified atmosphere in a closed fermentation vessel were known at the time of the invention. Izumi teaches of a method of making soy based seasoning where the fermentation of soy sauce takes place in large batches in a closed type tank in order

to reduce the fermentation time of the soy based seasoning (abstract and Column 2). Izumi reference teaches that the moromi (i.e., unrefined soy or soy koji with water after the koji formation step) when ferments includes carbon dioxide, which needs to be removed from the fermenting moromi in order to speed up the fermentation process. The removal of carbon dioxide is done by providing a ventilation gas which can be oxygen including gas, such as air or an inert gas (i.e., a gas that is inactive to the unrefined soy or moromi (Column 3, line 25 to Column 4, line 7). The reference further teaches that excess of oxygen oxidizes the unrefined soy and deteriorates the quality of the finished product, thus inert gas atmosphere is preferred. Izumi also teaches of nitrogen as the preferred inert gas (Column 4, lines 4-7). Regarding the amount of nitrogen in the tank, Izumi teaches that the feeding rate of the inert gas may be varied in accordance with the raw material of moromi, temperature of fermentation etc., in the fermentation tank (Column 4, lines 8-13). The reference further teaches that for a 1000-liter fermentation tank, the volume of inert gas circulated is 700-1500 liter per hour (column 4, lines 10-21). In an example the reference teaches that 167-ton of water and 12 ton of koji along with 250 Kg (i.e., 0.25 ton) of malt in a 200 Kiloliter tank (Column 7, lines 18-20). It is noted that 1 ton is approximately equal to 1.132 kiloliters, thus by that conversion 167 tons of water =167 X1.1 =184 Kiloliter capacity
Assuming that koji and malt occupy very little space and weigh negligible then the percent of occupied volume in the tank would be about 92% (i.e., [(184/200) X100=92]). Thus the volume of the fermentation tank headspace would fall in the range of about 8% in case of the example, based on the discussion above. Thus the reference teaches that the headspace of the closed fermentation tank is in the range of about 8%, which would be considered to be 10% for the ease of calculation. The reference also teaches of volume of nitrogen can be varied and that the volume is generally 0.7 to 1.5 times the total volume of the fermentation tank as discussed above (column 4, lines 10-21). Therefore, based on the above information the volume of nitrogen purged into the fermentation tank in a closed type fermentation system is about 7-15 times the headspace, which includes applicant's recited range in claims 11and 12 as instantly claimed. Thus introducing an inert gas, such as nitrogen, in a closed type fermentation

system (as instantly claimed), in the volume range recited by the applicant was known at the time of the invention. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify Baensch in view of Izumi and flush the fermentation tank/ vessel with nitrogen in the volume ratio as taught by Izumi in order to remove the carbon dioxide without introducing excessive amounts of oxygen in order to shorten the brewing period of soy based seasoning without compromising the quality of the finished product as taught by Izumi (Column 3, lines 25 to Column 4, line 53).

NOTE: Regarding the above limitation of the volume of nitrogen in relation to the headspace as recited in claims 11-12, applicant is further referred to the rejection under 35USC 112 above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Chawla whose telephone number is (571) 272-8212. The examiner can normally be reached on 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jyoti Chawla
Examiner
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KEITH HENDRICKS
PRIMARY EXAMINER